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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,093	04/11/2005	Udi Damari	26479U	6784
20529	7590	11/16/2007		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER SKOWRONEK, KARLHEINZ R	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 11/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/519,093	Applicant(s) DAMARI ET AL.	
	Examiner Karlheinz R. Skowronek	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75-90 is/are pending in the application.
- 4a) Of the above claim(s) 89-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/29/07;8/18/06;6/6/06;7/19/05.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 24 August 2007 is acknowledged.

Claims 89-90 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to the nonelected group II, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 24 August 2007.

Claim Status

Claims 75-90 are pending.

Claims 1-74 are cancelled.

Claims 89-90 stand withdrawn as being directed to a non-elected invention.

Claims 75-88 are being examined.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on 29 October 2007, 18 August 2006, 06 June 2006, and 19 July 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statements.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: Application 60/391,575, filed on 27 June 2002, was filed more

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than one year before the filing of PCT/IL03/00544, filed on 29 June 2003, and thus does not meet the provisions of 35 USC 119(e). Thus, the effective filing date for this application is 10 October 2002.

Specification

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, specification p. 4. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01; and

The use of the trademark EMBRYOGUARD (p. 29, 30, 31 and 32) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

It is noted that the Preliminary amendment to the claims filed 27 December 2004 is a non-compliant amendment. However in the interest of compact prosecution, the preliminary amendment of the claims will be entered and the claim examined. It is requested that in order to prevent delays in prosecution, applicant should appropriately indicate the status and any modifications made in future amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 75-88 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gianaroli et al. (Human Reproduction, Vol. 15 No. 10, p 2241-2246, 2000), in view of Whisler et al. (Clinical Chemistry, Vol. 36, No9, p. 1587-1588, 1990).

The claims are directed to a method of controlling the processing of components involved in an *in vitro* fertilization (IVF) in which a matching set of two or more components are defined; each of the components is assigned a unique machine-readable identification mark; providing on each component the identification mark; reading the identification mark of a component to verify that the component belongs to the matching set. In some embodiments, the components that are marked are consists of holders, physician, embryos, oocytes, spermatozoa. In some embodiments, the matching set includes an embryo and a recipient. In some embodiments, the identification mark assigned to components is different. In some embodiments, the matching set includes a sperm and an oocyte. In some embodiments, a matching set corresponds a biological entity and a holder. In some embodiments, an entity is within a holder and the holder is labeled. In some embodiments, the identification marks assigned to the components are the same. In some embodiments, the patient and their records are matched through the assignment of an identification mark. In some

embodiments, the barcode is readable by scanning. In some embodiments, the identification mark is a barcode. In some embodiments, the identification mark is an image readable mark. In some embodiments, a label having the identification mark is affixed to a holder.

Gianaroli et al. shows a method for controlling the processing of components used in *in vitro* fertilization. Gianaroli et al. shows that a matching set of two or more components is defined and that the components are assigned a unique identification (p. 2243, col. 1, sect 4). Gianaroli et al. shows that unique identification mark is used to verify the components belong to the correct patients (2243, col. 1, sect. 4). Gianaroli et al. shows an embodiment the components that are marked are consists of holders, physician, embryos, oocytes, and spermatozoa (p. 2243, col. 1 -2244, col. 1). Gianaroli et al. shows in an embodiment, that the identification mark assigned to components is different (p. 2244, col. 1, sect. 7.2). Gianaroli et al. shows in an embodiment that the matched set is an embryo and a recipient (p. 2245, col. 1-2). Gianaroli et al. shows in an embodiment that the matching set includes a sperm and an oocyte (p. 2243, col. 1, sect. 4). Gianaroli et al. shows an embodiment in which an entity is within a holder and the holder is labeled, reading on the embodiments of at least an entity is within a holder, where the holder is labeled with identification mark and a matching set corresponding to a biological entity and a holder (p. 2245, col.2, sect. 12.6). Gianaroli et al. shows that the identification marks assigned to the components are the same (2243, col. 1, sect. 4). Gianaroli et al. shows an embodiment in which the patient and their records are matched through the assignment of an identification mark (p. 2241, col. 2 sect 2).

Gianaroli et al. does not show that the unique identification is machine-readable.

Whisler et al. shows use of machine-readable identification marks and shows the identification marks are used to control the automatic processing of medical specimens. Whisler et al. shows that the machine-readable identification mark is a barcode (p. 1588, col. 1). Whisler et al. shows that bar-coding is highly accurate and machine-readable information is more reliable than manually entered data (p. 1588, col. 2). Whisler et al. shows that the barcode is readable by scanning (p. 1588, col. 2). Whisler et al. shows the identification mark is an image readable mark (p. 1588, figure 1). Whisler et al. shows that a label having the barcode is affixed to a specimen tube label (p. 1588, col. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify procedures of processing IVF components of Giananroli et al. with the use of barcodes in medical specimen processing of Whisler et al. because Whisler et al. shows that bar-coding is highly accurate and machine-readable information is more reliable than manually entered data.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

13 November 2007

/KRS/

Karlheinz R. Skowronek

Assistant Examiner, Art Unit 1631

/John S. Brusca/

Primary Examiner

Art Unit 1631